

## AUG U 2 2007

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Pages Via Fa Commissioner for I P. O. Box 1450 Alexandria, VA 22		I hereby certify that t	his correspondence is being facsimile Patent and Trutemark Office (fax no. 150), 2007.
Regarding the follo	wing Application:		
Applicant(S):	STEINER, Mitchell S. et al.	Examiner:	Fubara, Blessing M
Serial No./ Patent No.:	10/747,686	Group Art Unit:	1618
Filed/Issued Date:	December 30, 2003	Attorney Docket No.	: P-2769-US9
Title:	A METHOD FOR CHE	MOPREVENTION C	OF PROSTATE CANCER
Please find:			
Transmittal Sheet Containing: Pages of Signed Declaration Peges of Larges of	ication Transmittal cheet eet Under 35 USC 111(a) Application Under 35 USC 111(b) for Entering National Phase eetification laims stract formal Drawings  a & Power of Attorney tion of Recordation of Assign. and or Sheet 'Recordation of Assign.	10. Response to No. 11. Request for Co. 12. Information Di. Form PIO/Si. Preliminary An. 14. Response to Oddated. 15. Petition for a Co. 16. Notice of Appe 17. Sauc Fee Tran. 18. Submission of Sheets of Copy of Priori 20. Claim for Com. Statement Us. Copy of Assignation of Statement Us. Copy of Assignation and Statement Us. Statement Us. Copy of Assignation and Statement	Thee Action  One Month(s) Extension of Time  al
8. Recordation of Ass	ign. Cover Sheet & Signed Assign	. 22. Other:	

## AUG U 2 2007

Attorney Docket No.: P-2769-US9

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

STEINER, Mitchell S. et al.

Examiner:

Fubara, Blessing M

Serial No.:

10/747,686

Group Art

Unit:

1615

Filed:

December 30, 2003

Title:

A METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

#### INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO-1449:

- 1. Iisting documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents, and/or United States patent applications, and/or United States patent application publications are not included in this information disclosure statement; and/or
- 2. listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Scrial No. 10/611,056, filed July 2, 2003 which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
- 3. I listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement 193355
- 4. Isiting other information for the Examiner's consideration which 18 was Deited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement/33/2367 MBLANCO 03000012 10747686

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APPLICANTS:

STEINER, Mitchell S. ct al.

SERIAL NO.:

10/747,686

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December 30, 2003

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The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

- I) Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or
- II) After the period specified in (1) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;
  - the undersigned hereby states that each item of information listed on the Form PIO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

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	2.	the undersigned hereby authorizes the Patent Office to charge the fee in
	the an	nount of \$180.00 under 37 C.F.R §1.17 (p) to Deposit Account 50-3355.
III)		After the period in (I) and (II) but before the payment of the issue fee and,
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		a) that each item of information cited on the form PTO-1449 was
		cited in a communication from a foreign Patent Office in a counterpart
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		Information Disclosure Statement; or
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		and
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Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted.

Mark S. Cohen

Attorney for Applicants Registration No. 42,425

Dated: August 1, 2007

PEARL COHEN ZEDEK LATZER LLP 1500 Broadway, 12th Floor New York, NY 10036

Phone: (646) 878-0800 Fax: (646) 878-0801

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO			1449A/PTO	Complete if Known		
				Application Number	10/747,686	
INF	ORMAT	<b>TION</b>	DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT			Y APPLICANT	First Named Inventor	STEINER, Mitchell S.	
	(use as many sheets as necessary)			Group Art Unit	1615	
(			Examiner Name	Not yet known		
Sheet	1	of	9	Attorney Docket Number	P-2769-US9	

<u> </u>			U.	S. PATENT DOCUMENTS		
Examiner Initials*	Cite, No.		cument od Code <sup>2</sup> wown)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	Α	4,990,538	Γ	Harris et al.	February 5, 91	
	В	5,788,964	<u> </u>	Baral et al.	August 4, 98	
	C	5,650,425		Biegnon et al.	July 22, 97	
	D	4,696,949		Toivola et al.	Sept 29, 87	
	E	5,491,173		Toivola et al.	Feb. 13, 1996	
	F	5,571,534		Jalonen et al.	Nov. 5, 1996	
	G	5,605,700		DeGregorio et al.	Feb. 2 <u>5, 1997</u>	
	Н	5,595,722		Grainger et al.	Jan. 21, 1997	
	1	5,599,844	į	Grainger et al.	Feb. 4, 1997	
	J	5,629,007	<u> </u>	Audia et al.	May 13, 1997	
	K	5,635,197		Audia et al.	June 3, 1997	
	L	5,595,985	<u> L</u>	Labrie	Jan. 21, 1997	
	M	5,441,986		Thompson, et al	08-15-1995	
	N	5,852,059		Thompson, et al	12-22-1998	
	0	5,827,892		Loeser, et al	10-27-1998	
	Р	5,821,254		Sporn, et al	10-13-1998	
	Q	5,859,045		Treppendahl, et al	01-12-1999	
	R	5,935,987		Treppendahl, et al	08-10-1999	
	s	2005/0171073		Steiner, et al	01-2006	

			FO	REIGN PATENT DOC	UMENT8		
Examiner Initials*	Cite, No.		gnPatent Docume Kind Co (if know	Mame of Patentee or de <sup>5</sup> Applicant of Cited Docum		Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	7°
	Т	wo	98/58634		December 30, 98		
ļ .	U	EP	415 623 A2	Harris et al	March 6, 1991		
	V	EP	616 529 B1		September 28, 94		
	W	EPC	095875		Dec 7, 1995		
	х	ΜΦ	95/26720	Biegon et al	Oct 12, 1995		
	Υ	wo	0008001		Feb 17, 2000		

Examiner Signature	Date Consi	dered	j

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the sertal number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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s	ubstitute for form 1449/VPTO	Complete if Known		
		Application Number	10/747,888	
INFO	RMATION DISCLOSURE	Filing Date	December 30, 2003	
STA	TEMENT BY APPLICANT	First Named Inventor	STEINER, Mitchell S.	
		Group Art Unit	1615	
(us	so as many sheets as necessary)	Examiner Name	Not yet known	
Sheet	2 of <sup>9</sup>	Attorney Docket Number	P-2769-US9	

		U.	S. PATENT DOCUMENTS		
Examiner Ini(ials*	Cile, No.	U.S. Patent Document  Number Kind Code <sup>2</sup> (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	z	4,329,364	Neri et al.	May 11, 1982	
	AA	4,474,813	Neri et al,	Oct. 2, 1984	
	AB	6,080,877	Swindell et al	June, 2000	
	AC	6,265,448	Steiner et al	July 24, 2001	
	AD	6,410,043	Steiner et al	June 25, 2002	
	AE	6,632,447	Steiner et al	Oct 14, 2003	
	AF	6,413,533	Steiner et al	July 2, 2002	
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	АН	6,413,535	Steiner et al	July 2, 2002	
	Al	4,996,225	Toivola et al	Feb 26, 1991	
	AJ	5,811,120	Gibson et al	Sept 22, 1998	
	AK	5,972,383	Gibson et al	Oct 26, 1999	
	AL	4,418,068	Jones	Nov 29, 1983	

			FOR	REIGN PATENT DOCUM	ENTS		
		Forei	gnPatent Document	Name of Patentee or	Date of Publication of	Pages, Columns, Lines,	
Examiner Initials*	Cite, No.	Office <sup>3</sup>	Number Kind Code (if known)	Applicant of Cited Document	Cited Document MM-DD-YYYY	Where Relevant Passages or Relevant Figures Appear	T°
	АМ	wo	94/12162	Warri et al	June 9, 1994		
	AN	wo	99/56739	Steiner et al	November 11, 1999		
	AO	wo	00/47214	Healey et al	August 17, 2000		
	AP	WO	96/09046	Audia et al	March 28, 1996		
	AQ	EP	0 670 162	Gibson et al	Sept 6, 1995		
	AR	wo	00/19998	KGK Synergize	04-13-2000		
	AS	wo	97/25038	Novo Nordisk	7-17-1997		
	AT	wo	99/08682	Duke University	02-25-1999		
,	ΑÜ	wo	97/25037	Novo Nordisk	7-17-1997		-

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<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 If possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTQ		Complete if Known			
			Application Number	10/747,688	
INFORMATION DISCLOSURE			I DISCLOSURE	Filing Date	December 30, 2003
STATEMENT BY APPLICANT (use as many sheets as necessary)		First Named Inventor	STEINER, Mitchell S.		
		Group Art Unit	1615		
		Examiner Name	Not yet known		
Sheet	3	of	9	Attorney Docket Number	P-2769-US9

		NON PATENT LITERATURE DOCUMENTS	
xaminer	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	ΑV	Greenwald "Expanding Horizons in Breast and Prostate Cancer Prevention and Early Detection", in J. Cancer Education, 1993, Vol. 8, No. 2, pages 91-107.	
	AW	Brawley et al., "Chemoprevention of Prostate Cancer" in Urology, 1994, Vol. 43, No. 5.	$\neg \sqcap$
	AX	Kelloff et al., "Introductory Remarks: Development of Chemopreventive Agents for Prostate Cancer" in Journal of Cellular Biochemistry, 1992, Supplement 1611: 1-8.	
	AY	Lucia et al., "Chemopreventive Activity of Tamoxifen, N-(4-Hydroxyphenyl)retinamide, and the Vitamin 1) Analogue Ro24-553 I for Androgen-promoted Carcinomas of the Rat Seminal Vesicle and Prostate" in Cancer Research, 1995, vol. 55, pages 5621-5627.	
	AZ	Potter et al., "A Mechanistic Hypothesis for DNA Adduct Formation By Tamoxifen Following Hepatic Oxidative Metabolism" in Carcinogenesis, 1994, Vol. 15, No. 3, pages 439-442.	
	ВА	Schneider Martin R. et al. "Nonsteroidal Antlestrogens and Partial Estrogens with Prostatic Tumor Inhibiting Activity", Cancer Research Clinical Oncology Springer-Verlag 1986, J Cancer Res Clin Oncol (1986) 112: 258-265, p. 258-265,	
	ВВ	Martel Celine et al. "Binding Characteristics of Novel Nonsteroidal Antestrogens to the Rat Uterine Estrogen Receptors", Pergamon, J. Steroid Biochem. Molec. Bio. Vol 64, No. 3-4, pp. 199-205, 1998.	
	ВС	Valavaara Ritva, MD, PhD "Reliability of Estrogen Receptors in Predicting Response To Antiestrogens", Oncology, Volume 11 Number 5 Supplement No. 4 p. 14-18.	
	BD	Richard Gams, MD "Phase III Trials of Toremifene vs Tamoxifen" Oncology Volume 11, Number 5, Supplement 4, May 1997	
	BE	Christian Rohlff et al. "Prostate Cancer Cell Growth Inhibition by Tamoxifen Is Associated With Inhibition of Protein Linase C and Induction of p21" The Prostate 37:51-59 (1998) ©1998 Wiley-Liss, Inc	
•	BF	Nevalanine et al. "Hormone Regulation of Human Prostate in Organ Culture" Cancer Ress, vol. 53, no. 21, 1993, pages 5199-5207, XO0021 17653.	
	BG	Gingrich et al., "Androgen-independent Prostate Cancer Progression in the TRAMP Model", in Cancer Research 57, November 1, 1997, pages 4687-4691.	
	ВН	Gingrich et al., "Pathalogic Progression of Autochthonous Prostate Cancer in the TRAMP Model", Prostate Cancer and Prostatic Diseases, 1999, 2, Pages 70-75.	
	ВІ	Gingrich et al., "Metastatic Prostrate Cancer in a Transgenic Mouse", in Cancer Research 56, September 15, 1996, pages 4096-4102.	
	ВЛ	Gershanovich et al., " A Phase III Comparison of Two Toremifene Doses to Tamoxifen in Postmenopausal Women with Advanced Breast Cancer", Breast Cancer Research and Treatment 45, 1997, Pages 251-262.	

Examiner	Date	
Signature	Considered	·

<sup>\*</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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	Substitu	te for fo	rm 1449B/PTQ	Complete if Known		
INFORMATION DISCLOSURE				Application Number	10/747,686	
				Filing Date	December 30, 2003	
STATEMENT BY APPLICANT			BY APPLICANT	First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1615	
(use as many sheets as necessary)			ets as necessary)	Examiner Name	Not yet known	
Sheet	4	of	9	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catelog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	вк	Hayes et al. "Randomized Comparison of Tamoxifen and Two Separate Doses of	1
		Toremifencin Postmenopausal Patients with Metastatic Breast Cancer", Journal of Clinical	
		Oncology, Vol. 13, No. 10, 1995, pages 2556-2566.	
	BL	Pyrhönen et al., "Comparison of Toremifene and Tamoxifen in Postmenopausal Patients with	
		Advanced Breast Cancer: a Randomized Double-blind, the 'Nordic' Phase III Study', British	
	<u> </u>	Journal of Cancer, 1997, 76(2), pages 270-277.	
	ВМ	Neubauer et al., "Endocrine and Antiprostatic Effects of Raloxifene (LY156758) in the Male	1
	↓	Rat", The Prostate 23, 1993, pages 245-262.	1
	BN	Pollard, "Prevention of Prostate-Related Cancers in Lobund-Wistar Rats", The Prostate 39,	
	<u> </u>	1999, pages 305-309.	
	ВО	Simard et al., "Keoxifene Shows Pure Antiestrogenic Activity in Pituitary Gonadotrophs",	1
		Molecular and Cellular Endocrinology 39, 1985, pages 141-144.	
1	BP	Perry "High Dose Toremilene for Estrogen and Progesterone Receptor Negative Metastatic	
ł		Breast Cancer: a Phase II Trial of the Cancer and Leukemia Group B (CALGB)", in Breast	
	<u> </u>	Cancer Res Treat - 1995; 26(1): 25-40	_
	BQ	Hictanen T "Open Phase II Study of High-Dose Toremifene as First-Line Therapy for	
<u> </u>	<del></del>	Advanced Breast Cancer" in Oncology - May 1997; 11(5 Suppl 4): 37-40.	_
}	BR	Black et al. "Uterine Bioassay of Tamoxifen, Trioxifene and a New Estrogen Antogonist	
	-	(LY117018) in Rats and Mice" in Life Sciences, 1980, Vol. 26, pp. 1453-1458	
	BS	Moore et al. "Regulation of Cytoplasmic Dihydrotestosterone Binding in Dog Prostate by	1
		177 -Estudiol", in J. Clin. Invest. © The American Society for Clinical Investigation, Inc.,	1
	<del> </del>	Vol. 63 March 1979, pages 351-357.	
	ВТ	Shirai et al. "Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-	
	ļ	Aminobiphenyl-Induced Rat Prostate Carcinogenesis" in Imt. J Cancer: 57, 224-228 (1994)	4
	BU	Greenwald et al. "Breast Cancer Prevention and Early Detection", pages 93-106.	
	BV	Shonfold et al. "Androgen Deprivation Therapy", Chapter 37, Section III/Prostate Cancer,	
	-	pages 467-477	
		Jordan VC "Toremifene As An Anticancer Agent", Cancer Invest 1990; 8(2) 271	
	BX	Karlsson S. et al. "A Two-Year Dietary Carcinogenicity Study Of The Antiestrogen	
	-	Toremifene In Sprague-Dawley Rats" Drug Chem Toxicol 1996 Nov; 19(4): 245-66.	
	BY	Powles TJ "Status Of Antiestrogen Breast Cancer Prevention Trials" Oncology (Huntingt)	
	<u> </u>	1998 Mar; 12(3 Suppl 5): 28-31.	
	BZ	Moon RC et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone	1
		Response Modifiers: Toremifene, RU 16117, Tamoxilen, Aminoglutethimide and	1
		Progesterone", Anticancer Res 1994 May-June; 14(3A): 889-93.	1

Examiner	Date	
Signature	Considered	

<sup>\*</sup> EXAMINER: thitial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, include copy of this form with next communication to applicant,

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Complete if Known Substitute for form 1449B/PTO **Application Number** 10/747,686 Filing Date December 30, 2003 INFORMATION DISCLOSURE STATEMENT BY APPLICANT STEINER, Mitchell S. First Named Inventor **Group Art Unit** 1615 (use as many sheets as necessary) **Examiner Name** Not yet known Attorney Docket Number P-2769-US9 Sheet of

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	Nevalainen MT et al. "Expression and Hormone Regulation Of Prolactin Receptors in Rat Dursal and Lateral Prostate", Endocrinology 1996 Jul; 137(7): 3078-88.	
		Foekens JA et al. "Expression Of Prostate-Specific Antigen (PSA) Correlates With Poor Response To Tamoxifen Therapy In Recurrent Breast Cancer", Br J Cancer 1999 Feb; 79(5- 6): 888-94.	
	CC	Brandes 1.1 et al. "Salutary Clinical Response Of Prostate Cancer To Antiandrogen Withdrawal: Assessment Of Flutamide In An In Vitro Paragdigm Predictive Of Tumor Growth Enhancement", Clin Cancer Res 1997 Aug; 3(8): 1357-61.	
	CD	Miyata E et al. "Effects Of Tamoxifen, An Anticstrogen, On Rat Prostate Carcinogenesis by 3,2'-Dimethyl-4-Aminobiphenyl And Testerone Do Not Support An Estrogen Role In Testerone Promotion", Prostate 1997 Apr 1;31(1)9-13.	
	CE	Pienta KJ et al. "A Phase II Evaluation Of Oral Tamoxifen And Intermittent Intravenous Vinblastine In Hormone-Refractory Adenocarcinoma Of The Prostate"., Am J Clin Oncol 1996 Oct; 19(5):500-3.	
	CF	Pienta KJ et al. "Inhibition Of Prostate Cancer Growth By Vinblastine And Tamoxifen", Prostate1995 May; 26(5): 270-4.	
	CG	Lippman SM et al. "Cancer Chemoprevention", J Clin Oncol 1994 Apr; 12(4):851-73.	
	СН	Szarka CE et al. "Chemoprevention Of Cancer", Curr Probl Cancer 1994 Jan-Feb; 18(1):6-79.	
	CI	Bergan RC et al. "A Phase II Study Of High-Dose Tamoxifen In Patients With Hormone-Refractory Prostate Cancer." Clin Cancer Res 1999 Sep; 5(9): 2366-73.	
	Cl	Chang William Y et al. "Estrogen Receptor-?: Implications For The Prostate Gland" The Prostate 40:115-124 (1999)	
	CK	Shughrue Paul J. et al. "Comparative Distribution Of Estrogen Receptor-? (Er-?) And ? (Er-?) mRNA In The Rat Pituitary, Gonad, And Reproductive Tract." Steroids 63: 498-504, 1998, Elsevier Science Inc.	
	CL	Prins Gail S. et al, "Neonatal Estrogen Exposure Up-Regulates Estrogen Receptor Expression in The Developing And Adult Rat Prostate Lobes*", Endocrinology 138: 1801- 1809, 1997)	
	СМ	Hempstock J. et al. "Growth Inhibition Of Prostate Cell Lines In Vitro By Phyto- Oestrogens", British Journal Of Urology (1998). 82. 560-563.	
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Examiner	Date	
Signature	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-98)

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s	ubstitut	a for fo	rm 1449B/PTO	Complete if Known		
INFORMATION DISCLOSURE				Application Number	10/747,686	
				Filing Date	December 30, 2003	
STAT	STATEMENT BY APPLICANT			First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1615	
(use as many sheets as necessary)			eets as necessary)	Examiner Name	Not yet known	
Sheet	8	of	9	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials"	Cite No.1	Include name of the author (In CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CP	"When Is Intervention Warranted?", Journal Of Cellular Biochemistry, Supplement 1611:138-139 (1992).	
	CQ	"Editorial: A New Actor In The Estrogen Receptor Drama-Entre ER-?", Endocrinology Vol. 138, No. 3, (1997).	
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	CU	Yu H et al. "Induction Of Prostate Specific Antigen Production By Steroids And Taxoxifen In Breast Cancer Cell Lines", Breast Cancer Res Treat 1994; 32(3)291-300.	
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	cw	Kangas L "Development And Biochemical Pharmacology Of Toremifene, An Antiestrogenic Antitumor Drug", Acta Obstet Gynecol Scand 1991; 70(4-5): 399.	
	ÇX	Anttila M et al. "Phurmacokinetics Of The Novel Antiestrogenic Agent Toremifene In Subjects With Altered Liver And Kidney Function" Clin Pharmacol Ther 1995 Jun; 57(6):628-35.	
	CY	Kamat AM et al. "Chemoprevention Of Urological Cancer", The Journal Of Urology, Vol. 161. 1748-1760. June 1999, p. 1748-1760.	
	CZ	Fleton SA "Potential New Antiestrogens For The Treatment Of Breast Cancer", Highlights in Oncology Practice Vol. 15, No. 2, 1997 p. 47-52	
	DA	Nevalainen M.T. et al. "Estrogen and Prolactin Regulation of Rat Dorsal and Lateral Prostate in Organ Culture", Endocrinology, Vol. 129, No. 2 pages 612-618	
	DB	Moon R.C. et al. "Chemoprevention of MNU-Induced Mammary Tumorigenesis by Hormone Response Modifiers: Toremifenc, RU 16117, Tamoxifen, Aminoglutethimide and Progesterone", Anticancer Research 14: 889-894 (1994)	
	DC	Price K. R. et al. "Naturally Occurring Oestrogens in Food - A review", Food Additives and Contaminants, 1985, Vol. 2, No. 2, 73-106.	

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Signature	Considered	

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PTO/SB/08A (10-86)

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	\$ubstit	ute for f	orm 1449B/PTO	Complete if Known		
INFORMATION DISCLOSURE				Application Number	10/747,686	
				Filing Date	December 30, 2003	
ST	STATEMENT BY APPLICANT			First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1615	
	(use as many sheets as necessary)			Examiner Name	Not yet known	
Sheet	7	of	9	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	DD	Cheng E et al. "Endocrinology Of The Prostate", Prostate Diseases, chapter 5- p. 57-71.	
	DE	Bonkhoff II et al. "Estrogen Receptor Expression in Prostate Cancer and Premalignant Prosatic Lesions", American Journal of Pathology, Vol. 155, No. 2 August 1999.	
	DF	"New Research Approaches in The Prevention And Cure Of Prostate Cancer", American Association For Cancer Research, December 1998	
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	DH	Landstrom M, et al. "Inhibitory Effects Of Soy and Ryc Diets On The Development Of Dunning R3327 Prostate Adenocarcinoma in Rats, The Prostate 36: 151-161 (1998).	
	Di	Buclke-Sam J. et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology And Reproductive And Developmental Testing", Reprod Toxicol 1998 May-June; 12(3):217-21.	
	DJ	Treinen KA et al. "An Evaluation Of The Novel Selective Estrogen Receptor Modulator, Idoxifene, For Effects On Reproduction in Rats And Rabbits:, Toxicol Sci 1998 Feb; 41(2):199-207.	
	OK	Bochm S et al. "Estrogen Suppression As A Pharmacotherapeutic Strategy In The Medical Treatment Of Benign Prostatic Hyperplasia: Evidence For Its Efficacy From Studies With Mepartricin" Wien Klin Wochenschr 1998 Dec 11; 110(23):817-23.	
	DL	Dhar JD et al. "Estrogen, Androgen and Antiestrogen Responses in The Accessory Organs Of Male Rats During Different Phases Of Life", Endocr Res 1998 May; 24(2): 159-69.	F
	DM	West Neal B et al. "Estrogen and Progestin Receptors And Aromatase Activity In Rhesus Monkey Prostate" Endocrinology, Vol. L. 123, (1998)	i
	DN	Strauss L "Genistein Exerts Estrogen-Like Effects In Male Mouse Reproductive Tract", Molecular and Cellular Endocrinology 144 (1998) 83-93, Elsevier Science Ireland Ltd.	•

Examiner	 Date	
Signature	Considered	

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Substitute for form 1449B/PTO				Complete If Known		
				Application Number	10/747,686	
INFORMATION DISCLOSURE			I DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT				First Named Inventor	STEINER, Mitchell S.	
				Group Art Unit	1616	
(use as many sheets as necessary)			eets as necessary)	Examiner Name	Not yet known	
Sheet	8	of	9	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS		
Examiner Cite Initials* No.*		Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	DO	Hobisch Alfred "Metastatic Lesions From Prostate Cancer Do Not Express Oestrogen And Progesterone Receptors" J. Pathol. 182: 356-361, 1997.		
<del>-</del>	DP	Albert David S. et al. "An Overview Of Clinical Cancer Chemoprevention Studies With Emphasis On Positive Phase III Studies" Overivew of Diet Cancer 6928-6975 (1995)		
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	DR	Kellof GJ et al "Strategies For Chemoprevention Of Prostate Cancer", Prostate Cancer and Prostate Disease (1988) 5, 107.		
. mast diliman	DS	Buelke-Sam Judy et al. "The Selective Estrogen Receptor Modulator, Raloxifene: An Overview Of NonClinical Pharmacology and Reproductive Development Testing", Reproductive Toxicology Vol. 12, No. 3 pp. 217-221, 1998.		
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	DU	Kuiper George G. J. M. "Cloning Of A Novel Estrogen Receptor Expressed In Rat Prostate And Ovary", Proc. Natl. Acad. Sci USA Vol. 93, pp. 5925-5930, June 1996 Biochemistry.		
	DV	Kuiper George G. J. M. "Interaction Of Estrogenic Chemicals and Phytoestrogens With Estrogen Receptor?", Endocrinology Vol. 139, No. 10 (1998).		
	DW	Horton John et al. "Tamoxifen In Advanced Prostate Cancer" An ECOG Pilot Study", The Prostate 12: 173-177 (1988).		
	DX	Hayes "A Randomized Comparison Of Tamoxifen, Trioxifene And A New Estrogen Antogonist (LY117018) In Rats And Mice" In Life Sciences, 1980, vol. 26, pp. 1453-1458.		
•	DY	Jordan Craig V. "Antiestrogenic Action of Raloxifene and Tamoxifen: Today and Tomorrow" Journal of National Cancer Institute, Vol. 90, No. 13, July 1, 1998		
	DZ	Warri Anni. M. et al "Apoptosis in Toremifene Induced Growth Inhibition of Human Breast Cancer Cells in Vivo and In Vitro" Journal of National Cancer Institute, Vol. 85, No. 17, September 1, 1993		
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Signature	Considered	

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	Application Number	10/747,686	
INFORMATION DISCLOSURE	Filing Date	December 30, 2003	
STATEMENT BY APPLICANT	First Named Inventor	STEINER, Mitchell S.	
	Group Art Unit	1615	
(use as many sheets as necessary)	Examiner Name	Not yet known	
heet 9 of 9	Attorney Docket Number	P-2769-US9	

		NON PATENT LITERATURE DOCUMENTS		
xaminer nilials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	EB	Krieg, Michael et al "Androgens and Estrogens: Their Interaction with Stroma and Epithelium of Human Benign Prostatic Hyperplasia and Normal Prostate" J. Steroid Biochem. Vol. 19, No. 1 pp. 155-161, 1983		
	EC	Hard, Gordon C. et al. "Major Difference in the Hepatocarcinogenicity and DNA Adduct Forming Ability between Toremifene and Tamoxifen in Female Crl: CD(BR) Rats" Cancer Research 53, 4534-4541, October 1, 1993		
	ED	Boyle Peter et al "Epidemiology of Prostate Cancer Chemoprevention" Eur Urol 1999: 35:370-376		
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	E!	Nevaluinen MT et al "Hormone regulation of human prostate in organ culture" Cancer Res. 1993 Nov 1:53 (21):5199-207		
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